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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/606,629    06/29/00    HEINICKE

G

EXAMINER

HM12/0823

NGUYEN, H

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

08/23/01

E BRENDAN MAGRAB  
FAULDING INC  
200 ELMORA AVENUE  
ELIZABETH NJ 07207

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

(201) 228-2163

E. Brendan Magrab

<b>Office Action Summary</b>	<b>Application No.</b> 09/606,629	<b>Applicant(s)</b> HEINICKE ET AL.	
	<b>Examiner</b> Helen Nguyen	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 60-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**Notice of References Cited**

Application/Control No.

09/606,629

Applicant(s)/Patent Under  
Reexamination  
HEINICKE ET AL.

Examiner

Helen Nguyen

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**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification	
	A	US-				
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification	
	N	WO 96/17598	06-1996		Sherman	--	--
	O						
	P						
	Q						
	R						
	S						
	T						

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

### **DETAILED ACTION**

The claimed priority to a continuation of application serial no. 09/287,904, now U.S. Patent 6,033,687, and 09/447,642 now U.S. Patent 6,214,385, and 09/169,792 now abandoned, and 09/814,602 now U.S. Patent 5,834,024, and a continuation in part of application serial no. 08/369,100 now abandoned, is acknowledged.

In applicants preliminary amendment paper no. 2, Applicants cancelled claims 1-48, adding claims 80-89, which were renumbered under rule 126 to claims 49-59.

The preliminary amendment of paper no. 3 is acknowledged. Applicants cancelled all pending claims and added new claims 91-101, which have been renumbered under rule 126 to claims 60-70.

Claims 60-70 are presented for examination.

### ***Specification objection***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 and/or 121 as follows: Applicants have not updated the status of 09/447,642 in the first paragraph of the specification

### ***Claim rejection***

The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- Claims 60-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vehicle comprising 1) a short lag pellet and 2) a coating layer sufficiently enveloped the core which provides the claimed

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functionally, does not reasonably provide enablement only a long lag uncoated pellet. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicants disclose the above-cited vehicle on page 5, lines 5 and 9. No other vehicles are disclosed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

- Claims 60-70 are rejected under **35 U.S.C. 102(e)** as being anticipated by Sherman (WO 96/17598).

Sherman teaches a pharmaceutical formulation comprising rapid and delayed release coated diltiazem beads (abstract) having the same dissolution profile as that claimed (see page 3, lines 1-6, page 15, example 3, table 3). Once a day for oral administration is specified (abstract).

Claims 60-70 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached on (703) 308- 4432 or supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen  
Patent Examiner

August 23, 2001



EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500